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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,355	07/06/2001	H. Craig Dees	PHO-122	5998

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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10/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/900,355	Applicant(s) DEES ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-11,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-11,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-05-07 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 9-11, and 36-37 are currently pending.

Response to Arguments

Claim Rejections - 35 USC § 103

4. Applicant's arguments filed 7-05-07 in reply to the rejection of claims 1, 9-11 and 36-37 under 35 USC 103(a) over Heitz et al. are moot in view of the new grounds of rejection set forth below.
5. Claims 1, 9-11, and 36-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Heitz et al. for the reasons of record, and further in view of Walker et al. (US Patent No. 3,563,750), and Gee et al.
6. The disclosure of Heitz et al. sets forth derivatives of fluorescein, wherein the derivatives of fluorescein comprises "one or more" substituents at eight different positions. Contrary to Applicant's assertions, and absent evidence to the contrary, the

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compositions of Heitz et al. include the "high halogenated xanthene" compounds and compositions according to the present invention.

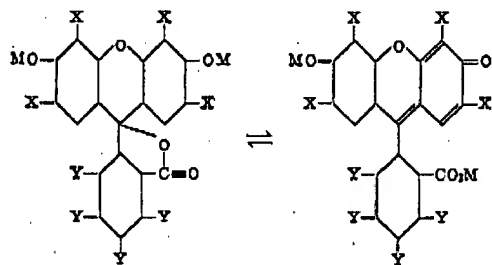
7. As stated in the prior Office Action, Heitz et al. discloses a photodynamic medicament comprising halogenated xanthene compounds, such as derivatives of fluorescein (Col. 4, lines 15-25). These derivatives may have one or more substitutes in the 4, 5, 6, 7, 2', 4', 5', and 7' positions selected from the group consisting of fluoro, chloro, bromo, iodo, and etc. (col. 4, lines 22-27). The disclosure therefore encompasses recited compounds such as monobromoerythrosin, tribromoerythrosin, 2',4,5,6,7,7'-tetrabromoerythrosin, and monochloroerythrosin.

Heitz et al. teach using buffers for the medicament, see col. 5, lines 10-25. With respect to using different vehicles for medicaments, such as capsules, pellets, boluses, salt blocks, see col. 5, lines 25-28.

Heitz et al. does not explicitly disclose the compounds of the instant invention.

Walker et al. discloses halogenated xanthene compounds according to the present invention comprising the following structure col. 3, lines 50-75:

These dyes may be represented by the formula notation:



Wherein M is hydrogen or a salt-forming cation, usually alkali metal, and normally sodium; X is hydrogen or halogen, normally chlorine, bromine or iodine (prefer- tetraphenylbiimidazole ably it is halogen, particularly bromine or iodine as in erythrosin and eosin); Y is hydrogen or halogen, normally chlorine, bromine or iodine (preferably it is chlorine as in Rose bengal, erythrosin and eosin).

Gee et al. (WO97/39064) disclose a compound having the structure of the recited 4, 5, 6, 7-tetrabromoerythrosin as in claim 3. Claim 3 recites a compound formula having two parts. The upper part relates to an xanthene:-related portion where R2-5 can be of iodine (I), and the lower part refers to a benzene ring where R13-15 can be of bromide (Br) (See claim 3, page 61-63). With respect to the features of "photodynamic treatment", applicant is reminded that a recitation of the intended use of the claimed invention, i.e. "photodynamic treatment", must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In regards to the intended use of the claimed compositions for various treatments and administrations, absent evidence to the contrary if the prior art structure is capable of performing the intended use, then it meets the claim.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to combine the teachings of Heitz et al., Walker et al. and Gee et al. in the design of the instantly claimed invention. One of ordinary skill in the art would have

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been motivated to modify the teachings of Heitz et al. with the compounds of Walker et al. and Gee et al. since the teachings of Heitz et al. clearly encompass the use of halogenated xanthene compounds having one or more substitutes in the 4, 5, 6, 7, 2', 4', 5', and 7' positions selected from the group consisting of fluoro, chloro, bromo, iodo, and etc. (col. 4, lines 22-27). Moreover, this disclosure therefore encompasses recited compounds such as monobromoerythrosin, tribromoerythrosin, 2',4,5,6,7,7'-tetrabromoerythrosin, and monochloroerythrosin, and also as disclosed within teachings of Walker et al. and Gee et al.

Declaration filed under 37 CFR 1.132

8. It is noted that the Declaration filed 7-05-07 by Dr. Hershey was not sufficient to overcome the new rejection set forth above since the disclosure of compounds such as monobromoerythrosin, tribromoerythrosin, 2',4,5,6,7,7'-tetrabromoerythrosin, and monochloroerythrosin, are clearly disclosed within the teachings of Walker et al. and Gee et al. Therefore, Applicant's assertions that the present invention is novel to the extent that synthesis of claimed compounds require highly specialized starting materials that must be combined in a very specific way to result in the claimed compounds is not supported by the specification as filed, which does not provide any guidance for synthesizing these compounds. Moreover, Applicant's Declaration appears to be an opinion expressed by Dr. Hershey since the Declaration does not set forth any evidence suggesting a significant level of unpredictability or difficulty in synthesizing the claimed compounds.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
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JLE